

REMARKS

This Amendment is submitted in response to the non-final Office Action dated November 28, 2007 (the "Office Action"). After entry of the present amendments, claims 1-31 and 33-34 will be pending in the application, with claims 6, 7, 16 and 20 being withdrawn from consideration. Claim 32 has been cancelled without prejudice, claim 29 has been amended to incorporate the subject matter of claim 32, claim 33 has been amended to depend from claim 29, and new claim 34 has been added. These amendments are fully supported by the originally-filed specification. New claim 34 finds support in the originally-filed specification at, for example, paragraph 26.

No new matter has been introduced. Applicants reserve the right to pursue the subject matter of any cancelled claim in one or more related applications.

Reconsideration of the present application in view of the following remarks is respectfully requested.

I. CLAIM REJECTIONS

A. Claims 1-3, 5, 8, 10-12, 15, 17-19, 22-24 and 27-31 Are Patentable Over U.S. Patent No. 5,112,305 to Barath *et al.*

In the Office Action, claims 1-3, 5, 8, 10-12, 15, 17-19, 22-24 and 27-31 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,112,305 to Barath *et al.* ("Barath"). Applicants respectfully disagree for at least the following reasons.

Independent claims 1, 15, and 27 recite "a plurality of micro-needles disposed upon the outer surface of the balloon" and independent claim 29 recites "the balloon has an outer surface having a plurality of micro-needles disposed thereon."

Barath does not disclose micro-needles as recited in the present claims. Instead, Barath discloses "a double lumen catheter that has additional tubular extensions projecting . . . from the outer surface of the outermost lumen. By abruptly increasing the pressure in the outer lumen, the tubular extensions deliver the therapeutic agent to locations deep within the lumen wall." Col. 2, lines 43-46. Barath further discloses that the tubular extensions have a diameter of 0.50 mm. Col. 3, lines 11-13.

There is no indication in Barath that the tubular extensions of Barath are micro-needles as claimed and described in the present specification. *See, e.g.*, Present Specification, ¶¶ [0027] and [0052]. As discussed in the present specification, micro-needle is a term of art

and generally means a needle having a diameter at most of about 100 μm , preferably less than about 10 μm , and a length of at most 1 mm. Present Specification, ¶¶ [0027] and [0052].

Accordingly, Barath does not disclose or suggest micro-needles.

Independent claim 27 recites that the plurality of micro-needles are disposed upon a plate, which is attached to said balloon wall in a manner such that the micro-needles project through the balloon wall. Barath fails to teach or suggest micro-needles disposed upon a plate. In addition, even if Barath's tubular extensions were considered to be micro-needles (which they are not), such tubular extensions are not disposed upon a plate.

Claim 29 has been amended to include the subject matter of claim 32 which the Examiner indicated would be allowable if rewritten in independent form. Thus, claim 29 is believed to be patentable over claim 29.

Accordingly, claims 1, 15, 27, and 29 and the claims depending therefrom are believed to be patentable over Barath. Thus, allowance of claims 1-3, 5, 8, 10-12, 15, 17-19, 22-24, and 27-31 are respectfully requested. New claim 34, which depends from claim 27, is also believed to be allowable for the reasons discussed above.

**B. Claims 1, 2, 4, 5, 15, 17-19, 27 and 28 Are
Patentable Over U.S. Patent No. 5,713,863 to Vigil *et al.***

In the Office Action, claims 1, 2, 4, 5, 15, 17-19, 27 and 28 are rejected under § 102(b) as allegedly being anticipated by U.S. Patent No. 5,713,863 to Vigil *et al.* ("Vigil"). Applicants respectfully disagree for at least the following reasons.

Independent claims 1, 15, and 27 recite "a plurality of micro-needles disposed upon the outer surface of the balloon" and independent claim 29 recites "the balloon has an outer surface having a plurality of micro-needles disposed thereon." Claim 1 also recites that "the micro-needles are capable of being ruptured." Vigil does not disclose or suggest micro-needles as claimed and described in the present specification. *See, e.g.*, Present Specification, ¶¶ [0027] and [0052]. As discussed in the present specification, a micro-needle is a term of art and generally means a needle having a diameter at most of about 100 μm , preferably less than about 10 μm , and a length of at most 1 mm. Present Specification, ¶¶ [0027] and [0052]. There is no indication in Vigil that the injectors of Vigil are micro-needles.

Vigil also does not disclose or suggest a balloon having an interior compartment for containing biologically active material as recited in claims 1 and 15. Instead, Vigil discloses an external fluid source 18 containing fluid medication. Col. 4, lines 50-60; col. 5, lines 29-30; Fig. 1.

Applicants respectfully submit that Vigil also fails to teach or disclose micro-needles capable of being ruptured as required by claim 1 and described in the present specification. *See, e.g.*, Present Specification, ¶¶ [0054] –[0056]; Figs. 9A, 9B, and 9C.

Independent claim 27 recites that “the micro-needles are disposed upon a plate, which is attached to said balloon wall in a manner *such that the micro-needles project through the balloon wall.*” (Emphasis added). Applicants respectfully submit that Vigil fails to teach or suggest micro-needles disposed on a plate such that they project through the balloon wall.

On page 3 of the Office Action, the Examiner states that Vigil discloses micro-needles disposed on plates and cites Figures 5B and 6B of Vigil in support. However, in Figures 2, 3, 4 and 7 of Vigil, the plate (42) is disposed on the exterior of element (30). Accordingly, the injectors in Vigil (which are not even microneedles) are not “disposed upon a plate, which is attached to said balloon wall in a manner such that the micro-needles project through the balloon wall.” Further, because the injectors in Vigil are disposed on a plate (42) that is disposed on the exterior of element (30), the plate is not attached to the inner surface of the balloon wall as recited in new claim 34.

For at least the foregoing reasons, it is believed that independent claims 1, 15, and 27 and the claims depending therefrom are patentable over Vigil. Accordingly, Applicants respectfully request that these claims be allowed and that this rejection be withdrawn. Also, new claim 34, which depends on claim 27, is believed to be allowable for the reasons discussed above.

C. Claims 9, 13, 14, 25 and 26 Are Patentable Over Barath in View of U.S. Patent No. 6,565,532 to Yuzhakov *et al.*

In the Office Action, claims 9, 13, 14, 25 and 26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Barath in view of U.S. Patent No. 6,565,532 to Yuzhakov *et al.* (“Yuzhakov”). Applicants respectfully disagree for at least the following reasons.

Claims 9, 13 and 14 depend from independent claim 1, which was shown above to be patentable over Barath. Claims 25 and 26 depend from independent claim 15, which was shown above to be patentable over Barath. In particular, Barath fails to disclose or suggest and, in fact, teaches away from a plurality of micro-needles disposed upon an outer surface of a balloon. As discussed above, micro-needle is a term of art and generally means a needle having a diameter at most of about 100 μm , preferably less than about 10 μm , and a length of

at most 1 mm. Present Specification, ¶¶ [0027] and [0052]. In contrast, Barath discloses tubular extensions that have a diameter of 0.50 mm (col. 3, lines 11-12). Thus, Barath does not disclose or suggest *micro*-needles.

Yuzhakov fails to cure the deficiencies of Barath. Yuzhakov does not even disclose or suggest the use of a catheter or a balloon. Instead, Yuzhakov is directed to the use of an array of micro-needles to apply semi-permanent or permanent markings to skin, or to apply semi-permanent subcutaneous makeup or other cosmetic compounds to skin (See Abstract). Thus, one of ordinary skill in the art would find no motivation to modify or combine the teachings of Barath and Yuzhakov to obtain the presently-claimed apparatus, particularly where Barath teaches away from the use of micro-needles.

For at least the foregoing reasons, it is believed that claims 9, 13, 14, 25 and 26 are patentable over Barath and Yuzhakov, either alone or in combination, and are therefore allowable. Accordingly, Applicants respectfully request that this rejection be withdrawn. New claim 34, which depends on claim 27, is also believed to be allowable for the reasons discussed above.

**D. Claims 9, 13, 14, 25 and 26 are Patentable Over
Vigil in View of Yuzhakov**

Claims 9, 13, 14, 25 and 25 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Vigil in view of Yuzhakov. Applicants respectfully disagree for at least the following reasons.

Claims 9, 13 and 14 depend from independent claim 1, which was shown above to be patentable over Vigil. Claims 25 and 26 depend from independent claim 15, which was shown above to be patentable over Vigil. In particular, Vigil fails to teach or suggest a plurality of micro-needles (claims 1 and 15) or micro-needles capable of being ruptured (claim 1). Vigil also does not disclose or suggest an interior compartment of a balloon for containing biologically active material. Applicants respectfully submit that Yuzhakov fails to cure the deficiencies of Vigil.

Yuzhakov does not even disclose or suggest the use of a catheter or a balloon. Instead, Yuzhakov is directed to the use of an array of micro-needles to apply semi-permanent or permanent markings to skin, or to apply semi-permanent subcutaneous makeup or other cosmetic compounds to skin (See Abstract). Thus, one of ordinary skill in the art would find no motivation to modify or combine the teachings of Vigil and Yuzhakov to obtain the presently-claimed apparatus.

For at least the foregoing reasons, it is believed that claims 9, 13, 14, 25 and 26 are patentable over Vigil and Yuzhakov, either alone or in combination, and are therefore allowable. Accordingly, Applicants respectfully request that this rejection be withdrawn. New claim 34, which depends from claim 27, is also believed to be allowable for the reasons discussed above.

II. ALLOWABLE SUBJECT MATTER

The Examiner indicated that claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Although Applicants disagree, claim 32 has been cancelled and claim 29 has been amended to incorporate the subject matter of cancelled claim 32. Also, claim 32 has been amended to depend from claim 29. Thus, it is believed that claim 29 and 33 are allowable. Accordingly, withdrawal of this objection and allowance of claims 29 and 33 are respectfully requested.

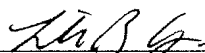
III. CONCLUSION

As the claim rejections and objection have been overcome, all claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Gidon D. Stern (Reg. No. 27,469)

By: 
Linda B. Azfin (Reg. No. 44,516)
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

Enclosure